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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,110

02/17/2004

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11502/34

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03/11/2008

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,110	Applicant(s) BLATTER ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered.

Claim Objections

2. Claim 12 is objected to because of the following informalities: On lines 3 and 6 it reads "adventital" and should rather read --adventitial--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 38 and 49 recite the limitation "the holding tabs" both in lines 3 and 4.

There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7, 12-23, 25-27, 31-34, 37-38, 41-45, 48-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Spence** (U.S. Patent No. **5,868,763**) in view of **Sauer** (U.S. Patent No. **5,697,943**).

Claims 1-7 and 12: Spence discloses a device and method for anastomosing a first vessel together with a second vessel comprising a first ring means **40'** for providing support and having holding surfaces that define a first ring opening for a first vessel at a first vessel opening, and a second ring means **40''** for providing support and having holding surfaces that define a second ring opening for a second vessel at a second vessel opening, wherein the holding surfaces contact the adventitial surfaces of the vessels, and the first ring means and the second ring means are configured to hold the first vessel and second vessel together with a holding means or surfaces comprising an anchor means **66**, and the ring means are configured to expand and contract to enable each respective vessel opening to change in diameter, and wherein the ring means are configured to be structurally linked in a manner such that the first and second ring means expand and contract in unison and such that the first vessel remains anastomosed to the second vessel at the first and second vessel openings as the first and second ring means expand and contract, and further comprising locking means for

locking the first ring means and the second ring means which include a guide means **104** for guiding the movement of one ring means relative to the other ring means, the rings being configured to cooperate with attachment actuation means **120** to move the device from a loading position to an anastomosis position (Figures 19-24; col. 9, lines 1-15).

Although the invention of Spence discloses performing an anastomosis in a minimally invasive manner to promote healing (col. 6, lines 46-51), the first ring means and the second ring means are not disclosed as holding the first vessel and second vessel together without requiring penetration.

Sauer teaches a first ring means and a second ring means ("first and second compression anastomosis device components") being configured to hold a first vessel and second vessel together without requiring penetration of at least one of the vessels (abstract; Figures 50 and 70). It would have been obvious to one of ordinary skill in the art at the time of invention to provide first and second ring means that do not penetrate the vessels, as taught by Sauer, to Spence since it was known in the art that avoiding tissue penetration is ideal in order to avoid tissue injury or tearing.

Claims 13-15: Spence discloses each ring comprising a plurality of flexible ("malleable") segments **50** having two adjoining arms in a V-shaped or U-shaped configuration, or an elliptical configuration (Figure 19).

Claims 16-17, 38, and 49: Spence discloses the claimed invention, including each flexible segment **50** being adjoined to an adjacent flexible segment by a connecting

joint, wherein each flexible segment has a flexible segment joint, except for the holding surfaces of each ring being holding tabs which extend from connecting joints.

Sauer teaches holding surfaces **260** of each ring being holding tabs which extend from connecting joints (Figures 5, 18 and 70; col. 9, lines 38-57). It would have been obvious to one of ordinary skill in the art at the time of invention to provide holding tabs, as taught by Sauer, to Spence since it was well known in the art for effectively holding tissue without causing injury or tearing.

Claims 18-20, 31-34, 37, 41-45, 48, and 52: Spence discloses the claimed invention, including each ring comprising a plurality of flexible segments **50** from which the respective holding surfaces extend, guides **104, 106** positioned to provide guided coaxial movement of the rings relative to each other in an interdigitated configuration, holding means including an anchor means **66**, and further comprising the plurality of flexible segments **50** enabling each ring means to radially expand to a deployed position, or change in diameter in response to changes in fluid pressure, after the first vessel and second vessel are anastomosed together or before the rings are locked together, such that each ring means and vessel opening has a greater diameter than the initial diameter of each respective ring means and vessel opening (col. 9, lines 1-15 and col. 14, lines 13-18).

Claims 21-23 and 25-27: Spence discloses the holding means of the first ring means and the holding means of the second ring means being in an interdigitated or mated configuration, due to the locking means **104, 106**, and the holding means and the locking means being separate structures (Figures 19-24).

7. Claims 8-10, 24, 28-30, 35-36, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Spence** (U.S. Patent No. **5,868,763**) in view of **Sauer** (U.S. Patent No. **5,697,943**), as applied to claims 7, 27, 31, and 42 above.

Claims 8-10, 24, 28-30, 35-36, and 46-47: Spence and Sauer disclose the claimed invention, including the guideposts or plurality of legs **106** having locking extensions (see circumferential elements on 106 in Spence), wherein the guideposts are positioned to slide into guides or slots **104** formed on another plurality of legs (the extensions or tabs onto which the holes 104 are formed) which frictionally engage the guideposts, wherein the guideposts, guides, and holding surfaces of the first ring, and the holding surfaces of the second ring are separate structures relative to each other (see Figures 19-24, Spence). Although each of the rings has both guideposts and guides (col. 15, lines 27-33), it would have been obvious to have all the guideposts on just one ring and all of the guides on the opposite ring since it was well known in the art to provide opposing mating holes to engage with protrusions, which is a common configuration for secure engagement between two interlocking members, and therefore one skilled in the art would recognize the possible modification.

8. Claims 11, 39-40, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Spence** (U.S. Patent No. **5,868,763**) in view of **Sauer** (U.S. Patent No. **5,697,943**), as applied to claims 7, 31, and 42 above, and further in view of **Green** (U.S. Patent No. **4,917,114**).

Claims 11, 40, and 51: Spence and Sauer disclose the claimed invention, except for the holding surfaces of at least the first ring being configured to capture vessel tissue in an everted configuration, and the step of positioning the second vessel being achieved in a manner such that the portion of the second vessel defining the second vessel opening is at least partially everted.

Green teaches holding surfaces of a first ring being configured to capture a body vessel tissue **2** in an everted configuration so that when the first ring and second ring are in an anastomosis position, an intimal layer **22** of the portion of the first vessel defining a first vessel opening contacts the portion of a second vessel **4** defining a second vessel opening, or wherein the step of positioning the second vessel is achieved in a manner such that the portion of the second vessel defining the second vessel opening **24** is at least partially everted (Figures 11-13). It would have been obvious to one of ordinary skill in the art at the time of invention to capture the openings of the vessels in an everted configuration, as taught by Green, to Spence and Sauer in order to create a ensure proper, sealed connection between the two vessels.

Claims 39 and 50: Spence and Sauer disclose the claimed invention, except for the second vessel being positioned on the second ring while simultaneously locking the first and second rings together.

Green teaches a second vessel **24** being positioned on a second ring **58** while simultaneously locking a first ring **62** with the second ring together (Figures 12-13). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Spence and Sauer by simultaneously locking the first ring with the second ring and positioning the second vessel on the second ring, as taught by Green, in order to facilitate coupling both the first and second vessels and the first and second rings together in an efficient manner.

Response to Arguments

9. Applicant's arguments with respect to claims 1-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731